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[FR Doc. 04–24532 Filed 11–2–04; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0215; FRL–7684–4]

Bacillus Pumilus Strain QST 2808; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the *Bacillus pumilus* strain QST 2808 in or on food commodities when applied/used in accordance with label directions. AgraQuest, Inc submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. Notification that EPA had received the petition was published on May 5, 2004 (69 FR 25092) (FRL–7354–4). This regulation eliminates the need to establish a maximum permissible level for residues of *Bacillus pumilus* strain QST2808.

DATES: This regulation is effective November 3, 2004. Objections and requests for hearings must be received on or before January 3, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under docket identification (ID) number OPP–2004–0215. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Barbara Mandula, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–7378; e-mail address: *mandula.barbara@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production/Agriculture (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

In the **Federal Register** of May 5, 2004 (69 FR 25092) (FRL–7354–4), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 4F6926) by AgraQuest, Inc, 1530 Drew Avenue, Davis, CA 95616. This notice included a summary of the petition prepared by the petitioner AgraQuest, Inc. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing a permanent exemption from the requirement of a tolerance for residues of *Bacillus pumilus* strain QST 2808. EPA previously had granted the petitioner a temporary exemption from the requirement of a tolerance for residues of *Bacillus pumilus* strain QST 2808, which was published on June 18, 2003 (68 FR 36476)(FRL–7301–1). That temporary exemption is set to expire June 30, 2006.

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) of the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .'' Additionally, section 408(b)(2)(D) of the FFDCA requires that the Agency consider ''available information concerning the cumulative effects of a particular pesticide's residues'' and ''other substances that have a common mechanism of toxicity.''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other

relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Bacillus pumilus strain QST 2808 is a ubiquitous and naturally occurring bacterium commonly found in soil. The results of the acute toxicology and pathogenicity studies previously submitted by the petitioner in support of its petition for a temporary exemption from the requirement of a tolerance for *Bacillus pumilus* strain QST 2808 indicate negligible to no mammalian toxicity. In addition, no pathogenicity was observed in any of the tests conducted with the *Bacillus pumilus* strain QST 2808 Technical product. Accordingly, the toxicology and pathogenicity data generated by AgraQuest, Inc in support of the temporary exemption from the requirement of a tolerance also support a permanent exemption from the requirements of a tolerance. This data is summarized in more detail below.

1. *Acute oral toxicity and pathogenicity (OPPTS 885.3050; MRID 451366–04)*. Fifteen male and fifteen female rats each were administered 4.1 x 10^9 colony forming unit (cfu) of *B. pumilus* strain QST 2808 Technical and observed for 14 days. Based on the data, *B. pumilus* strain QST 2808 does not appear to be toxic, infective, and/or pathogenic in rats, when dosed at 4.1 x 10^9 cfu/animal. Classification: Acceptable; Toxicity Category IV.

2. *Acute dermal toxicity (OPPTS 885.3100; MRID 451366–05)*. Five male and five female rabbits were dermally treated with 2g/kg body weight *B. pumilus* strain QST 2808 Technical for 24 hours and observed for the following 14 days. The acute lethal dose $(LD)_{50}$ is greater than 2,000 mg/kg. Classification: Acceptable; Toxicity Category III.

3. *Primary eye irritation (OPPTS 870.2400; MRID 452679–01)*. Three male rabbits each were administered 0.1 milliliters (mL) of QST 2808 Technical in the everted lower lid of one eye and then observed for 72 hours. Based on the data, QST 2808 Technical showed minimal effects to the eye. Classification: Acceptable; Toxicity Category IV.

4. *Acute injection toxicity/ pathogenicity (OPPTS 885.3200; MRID 451366–07)*. Eighteen male and eighteen female rats each were dosed at 1.6 x 10^8 cfu *Bacillus pumilus* strain QST 2808 Technical intravenously and monitored over a period of 28 days. A gross necropsy was performed on all rats. Based on the data, the test organism was not toxic, infective, or pathogenic to rats. Classification: Acceptable.

5. *Acute pulmonary toxicity/ pathogenicity (OPPTS 885.3150; MRID 451366–06)*. Eighteen male and eighteen female rats each were administered 1.6 x 10^8 cfu *Bacillus pumilus* strain QST 2808 Technical in a single intratracheal dose and monitored over a period of 35 days for clinical signs of toxicity. Necropsy studies showed no significant signs of abnormalities due to the test organism. Based on the data, *B. pumilus* strain QST 2808 was not toxic, infective, and/or pathogenic to rats when dosed at 1.6 x 10^8 cfu/animal. Classification: Acceptable.

6. *Acute inhalation toxicity (OPPTS 870.1300)*. Results of the acute pulmonary toxicity/pathogenicity (MRID 451366–06) performed with *Bacillus pumilus* strain QST 2808 Technical indicate that it is not toxic, infective, and/or pathogenic to rats when dosed at 1.6 x 10^8 cfu/animal. For the purposes of this specific action, the Agency has determined that the acute pulmonary toxicity/pathogenicity data are adequate to support and/or fulfill this particular data requirement.

7. *Primary dermal irritation (OPPTS 870.2500; MRID 452679–02)*. Each of three male adult rabbits were treated dermally with 0.5 mL QST 2808 Technical for 4 hours and observed for the following 72 hours. Based on the data, no abnormal clinical signs were noted. Approximately 60 minutes after patch removal, very slight erythema was noted on one of the three rabbits with resolution by 24 hours. When dosed with QST 2808 Technical at 0.5 mL/ animal, QST 2808 Technical was essentially non-irritating. Classification: Acceptable; Toxicity Category IV.

8. *Hypersensitivity incidents (OPPTS 885.3400)*. The registrant has reported no incidents to date. Nonetheless, pursuant to FIFRA section 6(a)(2), the registrant is required to report to the Agency any future incidents of hypersensitivity associated with *Bacillus pumilus* strain QST 2808.

9. *Hypersensitivity study (OPPTS 870.2600; MRID 460295–09)*. Twenty female guinea pigs were dosed on shaved skin once a week for 3 weeks with 0.4 mL of QST 2808 Technical. When challenged 14 days after the last induction, no signs of sensitization appeared. Acceptable.

10. *Immune response*. There is no information to suggest that *B. pumilus* strain QST 2808 has an effect on the immune system. The submitted toxicity/ pathogenicity studies in rodents indicated that following several routes of exposure, the immune system is still intact and able to process and clear the active ingredient (MRID 451366–04; 451366–06, 451366–07).

Based on the data generated in accordance with the Tier I data requirements set forth in 40 CFR § 158.740(c), the Tier II and Tier III data requirements were not triggered and, therefore, not required in connection with this action. In addition, because the Tier II and Tier III data requirements were not required, the residue data requirements set forth in 40 CFR § 158.740(b) also were not required.

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of the FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Most importantly, there is no evidence of adverse effects from oral, dermal, or inhalation exposure to this microbial agent. (See Unit III. Toxicological Profile.)

A. Dietary Exposure

Humans and animals are commonly exposed to *B. pumilus* strain QST 2808, a ubiquitous microorganism that inhabits soil. No toxicological endpoints were identified for *B. pumilus* strain QST 2808. The low toxicity and non-pathogenicity/infectivity of *B. pumilus strain* QST 2808 is demonstrated by the data summarized in Unit III. of this action.

1. *Food*. While the proposed use pattern may result in dietary exposure with possible residues in or on agricultural commodities, negligible to no risk is expected for the general population, including infants and children, or animals because *B. pumilus* strain QST 2808 technical demonstrated no pathogenicity or oral toxicity at the maximum doses tested, as noted above (Unit III.).

2. *Drinking water exposure*. The potential for transfer of *B. pumilus* strain QST 2808 to surface or ground water during run-off associated with intended use applications is considered minimal to non-existent, due to its percolation through and resulting capture in soil. Accordingly, the use of this microbial pest control agent on terrestrial plants is not anticipated to negatively impact the quality of drinking water.

B. Other Non-Occupational Exposure

Based on the proposed agricultural and horticultural use patterns, the potential for non-dietary exposures to *B. pumilus* strain QST 2808 pesticide residues by the general population, including infants and children, is unlikely. Accordingly, the Agency believes that the potential aggregate non-occupational exposure, derived from dermal and inhalation exposure through the application of *B. pumilus* strain QST 2808 as a pesticide, should fall well below EPA's currently tested microbial safety levels.

1. *Dermal exposure*. The potential for dermal exposure to *B. pumilus* strain QST 2808 pesticide residues for the general population, including infants and children, is unlikely because potential use sites are agricultural and horticultural. However, since *B. pumilus* strain QST 2808 is a naturally occurring bacterium in soil, there is a great likelihood of prior exposure for most, if not all individuals. Accordingly, the increase in dermal exposure due to pesticidal use of *B. pumilus* strain QST 2808 would be negligible. Furthermore, and as demonstrated in Unit III. of this action, the organism is of low dermal toxicity, the acute LD_{50} is greater than 2,000 mg/kg, and the QST 2808 Technical was essentially non-irritating (Toxicity Category IV). Accordingly, the risks anticipated for this route of exposure are considered minimal.

2. *Inhalation exposure*. Inhalation exposure to *B. pumilus* strain QST 2808 pesticide residues for the general population, including infants and children is unlikely because potential use sites are agricultural and horticultural. However, since *B. pumilus* strain QST 2808 is a naturally occurring bacterium in soil, there is a great likelihood of prior exposure for most, if not all individuals. Accordingly, the increase in exposure due to pesticidal use of *B. pumilus* strain QST 2808 would be negligible. Furthermore, and as demonstrated in Unit III. of this action, the acute pulmonary toxicity/pathogenicity testing performed on the technical formulation did not demonstrate pathogenicity or toxicity of *B. pumilus* strain QST 2808. (See Unit III.) Accordingly, the risks anticipated for this route of exposure are considered minimal.

V. Cumulative Effects

Section 408(b)(2)(D)(v) of FFDCA requires the Agency, when considering whether to establish, modify, or revoke a tolerance, to consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

These considerations include the possible cumulative effects of such residues on infants and children.

The Agency has considered the potential for cumulative effects of *B. pumilus* strain QST 2808 and other substances in relation to a common mechanism of toxicity. *B. pumilus* strain QST 2808 is practically non-toxic to mammals. Because no mechanism of pathogenicity or toxicity in mammals has been identified for this organism (see Unit III.), no cumulative effects from the interaction of residues of this product with other related microbial pesticides are anticipated when this product is used as directed on the label and in accordance with good agricultural practices.

VI. Determination of Safety for U.S. Population, Infants and Children

There is a reasonable certainty that no harm to the U.S. population, including infants and children, will result from aggregate exposure to residues of *B. pumilus* strain QST 2808 due to its use as a microbial pest control agent. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. As discussed previously, *B. pumilus* strain QST 2808 is not pathogenic or infective and is practically non-toxic to mammals. (See Unit III.) Accordingly, exempting *Bacillus pumilus* strain QST 2808 from the requirement of a tolerance should be considered safe and pose no significant risk.

FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure, unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are incorporated into EPA risk assessments either by 1) using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans, or 2) using a margin of exposure analysis. Due to the ubiquitous nature of *B. pumilus* strain QST 2808, residues of this microbial pesticide in or on agricultural commodities are not expected to significantly increase exposure to the U.S. population, including infants and children. Here, EPA concludes that the toxicity and exposure data are sufficiently complete to adequately address the potential for additional sensitivity of infants and children to residues of *B. pumilus* strain QST 2808 and that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to *B. pumilus* strain QST 2808 residues. Thus, the Agency has determined that the additional margin of safety is not necessary to protect infants and children, and that not adding any additional margin of safety will be safe for infants and children.

VII. Other Considerations

A. Endocrine Disruptors

EPA is required under section 408(p) of the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) ''may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate.'' Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there is no scientific basis for including, as part of the screening program, the androgen and thyroid hormone systems in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, *Bacillus pumilus* strain QST 2808 may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

To date, based on available data, the Agency has no information to suggest that *Bacillus pumilus* strain QST 2808 has an effect on the endocrine systems. Moreover, as is expected from a non-pathogenic microorganism that is practically non-toxic to mammals, the submitted toxicity/pathogenicity studies in rodents indicate that following several routes of exposure, the immune system is still intact and able to process and clear the active ingredient. (''BPPD Review''- 1/7/02). Thus, there is no

impact via endocrine-related effects on the Agency's safety finding set forth in this final rule for *Bacillus pumilus* strain QST 2808.

B. Analytical Method(s)

The Agency proposes to establish an exemption from the requirement of a tolerance without any numerical limitation for the reasons stated above, including *Bacillus pumilus* strain QST 2808's lack of mammalian toxicity. For the same reasons, the Agency has concluded that an analytical method is not required for enforcement purpose for *Bacillus pumilus* strain QST 2808.

C. Codex Maximum Residue Level

There is no Codex Alimentarius Commission Maximum Residue Level for *Bacillus pumilus* strain QST 2808.

VIII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2004–0215 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before January 3, 2005.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VIII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2004–0215, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

IX. Statutory and Executive Order Reviews

This final rule establishes an exemption from the requirement of a tolerance under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and

responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

X. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 13, 2004.

James Jones,

Director, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.1255 is added to subpart D to read as follows:

§ 180.1255 Bacillus pumilus strain QST 2808; Exemption from the Requirement of a Tolerance..

An exemption from the requirement of a tolerance is established for residues of the microbial pesticide *Bacillus pumilus* strain QST 2808 when used in or on all agricultural commodities when applied/used in accordance with label directions.

[FR Doc. 04–24250 Filed 11–2–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0206; FRL–7683–2]

Thifensulfuron-methyl; Tolerance Actions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is reinstating corn tolerances for the herbicide thifensulfuron-methyl. These corn tolerances were previously established but inadvertently removed shortly thereafter. Registrations under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for use of thifensulfuron-methyl on corn currently exist and have existed for more than 10 years.

DATES: This regulation is effective November 3, 2004. Objections and requests for hearings must be received on or before January 3, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit III. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under docket identification (ID) number OPP–2004–0206. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Joseph Nevola, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8037; e-mail address:*Nevola.joseph@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any